

REMARKS

Claims 34-42 currently appear in this application. The Advisory Action of February 9, 2004, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

As claims 19-33 have been cancelled, it is respectfully submitted that the rejections of claims 19-33 in the Office Action of October 31, 2003, are now moot.

It is respectfully submitted that the specification as filed enables one skilled in the art to use the herein claimed invention, as required by *In re Gosteli*, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). The present inventors discovered that inhibiting the effects of TNF-alpha is effective in treating hepatitis. In the present claims, the compounds that inhibit the effects of TNF alpha are etanercept and infliximab, both of which are compounds which have been found to be effective in treating rheumatoid arthritis by neutralizing the activity of secreted TNF. Since both etanercept and infliximab are compounds which have historically been used to treat rheumatoid arthritis, one

skilled in the art could readily determine a dosage of either of these compounds that would be useful in treating hepatitis.

For example, as noted in the MPEP Section 2164.01©, it is not necessary to specify the dosage or method of use if it is known to one skilled in the art that such information could be obtained without undue experimentation. If one skilled in the art, based on knowledge of compounds having similar physiological or biological activity, would be able to discern an appropriate dosage or method of use without undue experimentation, this would be sufficient to satisfy 35 U.S.C. 112, first paragraph.

Etanercept and infliximab both work by neutralizing the activity of TNF-alpha. Therefore, a physician who is familiar with dosages of etanercept or infliximab for treating rheumatoid arthritis by neutralizing the effects of TNF-alpha would be able to administer an amount of etanercept or infliximab sufficient to neutralize the effects of TNF-alpha so as to treat hepatitis, since the present inventors discovered the anti-hepatitis effects of the TNF-alpha inhibitors when patients were given a standard dose for treatment of rheumatoid arthritis.

In the declaration of Steven B. Abramson, M.D., submitted herewith, treatment of several patients with etanercept is described. As noted in the declaration, at the

time this treatment was begun, it was expected that TNF blockers high exacerbate chronic hepatitis C infection, and therefore treating hepatitis with TNF blockers was contraindicated. In fact, the abstract of Peterson et al., submitted with the declaration, expressed concern even as late as November, 2003, that treatment with infliximab or etanercept was contraindicated for patients with hepatitis C infection. However, the present inventors obtained some positive results.

As the examiner is well aware, treatment need not be 100% effective to be patentable. In the present case, not all of the patients treated with a TNF-alpha blocker responded positively. **However, three of the seven patients did respond favorably, indicating that this treatment is effective, although not for all patients.**


The Examiner noted in her Advisory Action of February 9, 2004, that, had claim 40 been limited to a method of treating viral hepatitis, the rejections as previously offered under 35 U.S.C. 102(b) would have been overcome. Claim 40 has now been so amended.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

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Respectfully submitted,

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